

AMENDMENTS TO THE CLAIMS:

Claims 1 - 33 (canceled)

34. (original) A pharmaceutical composition comprising:

i. a microemulsion comprising a lipid core and an amphipathic lipid layer surrounding said lipid core comprising positively charged lipids, wherein a hydrophobic portion of said amphipathic lipid layer is associated with said lipid core and a hydrophilic portion of said amphipathic lipid layer is associated with a hydrophilic surface of said amphipathic lipid said amphipathic lipid;

ii. a polynucleotide; and

iii. optionally, a lipidized polymer;

said amphipathic lipid being included in said composition in an amount effective to form a microemulsion with said lipid core, and said lipidized polymer being included in said composition in association with said amphipathic lipid in an amount ranging from about 0.01% to about 65% by weight of said composition.

35. (original) The composition according to claim 34 wherein said polynucleotide is associated with said positively charged lipid at the surface of said microemulsion.

36. (original) The composition according to claim 34 wherein said amphipathic lipid includes an amount of a steroid component effective to increase the stability of said amphipathic lipid.

37. (original) The composition according to claim 34 wherein said amphipathic lipid comprises a phospholipid.

38. (original) The composition according to claim 34 wherein said phospholipid is selected from the group consisting of phosphatidylcholine, cephalin, isolecithin, phosphatidylethanolamine, distearoylphosphatidylcholine, phosphatidylserine,

phosphatidylglycerol, phosphatidic acid, phosphatidylinositol, sphingomyelin, dimyristoylphosphatidylcholine, dimyristoylphosphatidylglycerol, pegylated phospholipids and mixtures, thereof.

39. (original) The composition according to claim 37 wherein said amphipathic lipid layer further comprises about 0.05% to about 25% by weight of a steroidal component.

40. (original) The composition according to claim 39 wherein said steroidal component is selected from the group consisting of cholesterol, pegylated cholesterol, coprostanol, cholestanol, cholestane, C₁ to C₂₄ steroidal esters and mixtures, thereof.

41. (currently amended) The composition according to claim + 34 wherein said ~~bioactive agent~~ polynucleotide is DNA.

42. (currently amended) The composition according to claim + 34 wherein said lipidized polymer is a lipidized protein or polypeptide.

43. (original) The composition according to claim 42 wherein said lipidized polypeptide is lipidized polylysine.

44. (original) The composition according to claim 42 wherein said protein is selected from the group consisting of enzymes, cell surface proteins, hormones, antibodies, growth factors, clotting factors, neuroproteins, tumor suppressors, toxins, antigens and epitopes of antigens, apolipoproteins, endogenous or exogenous tumor antigenic proteins, bioinvasive molecules (like bacterial invasins), lectins, lectin-like molecules, bacterial toxins such as cholera and macromolecules with bioadhesive properties.

45. (original) The composition according to claim 44 wherein said protein is selected from immunoglobulins, epitopes, transferrin, avidin, hormones, enzymes, integrin, apolipoprotein E, apolipoprotein B100, and mixtures, thereof.

46. (original) The composition according to claim 44 wherein said protein is lysozyme, avidin, apolipoprotein B100 or apolipoprotein E.
47. (original) The composition according to claim 34 wherein said lipid core comprises a mono-, di- or triglyceride.
48. (original) The composition according to claim 47 wherein said lipid core comprises triglycerides.
49. (original) The composition according to claim 48 wherein said triglyceride is triolein.
50. (original) A method of enhancing the delivery of a polynucleotide to a predetermined site or tissue within a subject comprising administering to said patient a composition according to any of claim 34 to said subject.
51. (original) A method of enhancing the delivery of a polynucleotide to a predetermined site or tissue within a subject comprising administering to said patient a composition according to any of claim 35 to said subject.
52. (original) A method of enhancing the delivery of a polynucleotide to a predetermined site or tissue within a subject comprising administering to said patient a composition according to claim 37 to said subject.
53. (original) A method of enhancing the delivery of a polynucleotide to a predetermined site or tissue within a subject comprising administering to said patient a composition according to claim 41 to said subject.
54. (original) The method according to claim 50 wherein said DNA is naked DNA.
55. (original) The method according to claim 51 said DNA is naked DNA.
56. (original) The method according to claim 53, said DNA is naked DNA.